EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Glooko, Inc.

579 University Avenue, Palo Alto, California, 94301, United States

Manufacturer SRN: US-MF-000023483

Authorised Representative Name

Glooko AB

Nellickevägen, 20 41263 Göteborg, Sweden

Scope:

- Software

Certificate Number:
28620163236

Revision:
00

Initial Certification Date:
21 December 2023

Certificate Decision Date:
21 December 2023

Certificate Issue Date:
21 December 2023

Certificate Expiry Date:
14 November 2028

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	**TD00334-01 Clooko Inc, Glooko Web Application**
Audit Report Reference	**Stage 1 audit ACTY-2022-609480**
	Stage 2 audit ACTY-2022-609481

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620163236

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PRODUCT LIST FOR CERTIFICATE

Issued to: Glooko, Inc

Certificate number: 28620163236

Certificate valid from: 2023-12-21

Product List Issue Date:
12 March 2025

Product	Classification and EMDN	Intended use[1]	Date Added
Software			
Basic UDI-DI: 0085509300MobileRef0023N			
REF-0002 - Glooko Mobile Application	Class IIa V92		2023-12-21
Basic UDI-DI: 0085509300REF-0009V8			
REF-0009 - Glooko XT Pro	Class IIa V92		2024-08-21
Basic UDI-DI: 0085509300REF-0010UR			
REF-0010 - Glooko XT Patient	Class IIa V92		2024-08-21
Basic UDI-DI: 0085509300WebAppRef001LF			
REF-0001 - Glooko Web Application	Class IIa V92		2023-12-21

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[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.